UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,071	03/24/2000	Stephen Pacetti	1225.001US1	2171

24201 7590 08/29/2005

FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
BUI, VY Q	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,071	PACETTI ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 29-55* is/are pending in the application.

4a) Of the above claim(s) *10-12,14-16,18,30-33,36,37,39,40,52 and 54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13,19-21,29,34,35,38,41-51,53 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application includes claims 10-12 (coiled/backbone stent), claims 18, 30-33 and 52 (wire stent), claims 14-16, 37, 39-40 and 54 (%W from 10%-30%, species III, see restriction paper #9) are directed to nonelected invention with traverse in Papers No. 10 and 13, therefore are withdrawn from further consideration as claims directed to non elected species.

Applicant's election with traverse of species of Fig. 5 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that it would not impose a serious burden on the Office to examine the identified species together in a single application. This is not found persuasive because the identified species are distinct and the Applicant fails to provide any evident to prove that they are indeed obvious variations of one to another. Without admission of obviousness from the Applicant, it would be a serious burden to the Examiner to prove/justify that each and every single identified species are patentable or unpatentable. The requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 recites the limitation "the underlying vessel morphology" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 19-21, 29, 34-35, 37-38, 43, 45, 51, and 53-54 are rejected under 35 U.S.C. 102(e) as being anticipated by FARIABI (6,419,693).

As to claims 19-21, 34-35 and 51, FARIABI (Fig. 5-7; abstract, lines 5-10; claim 1) discloses a radiopaque stent 50 of Cobalt-Chrome alloy comprising up to 20% of a radiopaque material such as tungsten (W). Stent 50 comprises tubular main body defining undulating pattern with holes. Stent 50 is carried by catheter 51 to be deployed in blood vessel 57 and expandable by balloon 54 (Fig. 6).

As to claims 43 and 45, FARIABI (claim 1) discloses a stent of 5%-35% Cr, 0%-20% W and 2%-40% Ni.

As to claim 29, FARIABI (Fig. 5-7) discloses a method of deploying radiopaque Co-Ni-Cr stent 50 to a lesion site 56 in blood vessel 57 as recited in the claim.

As to claim 38, the radiopaque material tungsten (W) in FARIABI stent has an atomic number of 74.

3. Claims 41-48 are rejected under 35 U.S.C. 102(e) as being anticipated by JALISI-US application 09/270,403 (filed 03/16/1999), which has been allowed on 5/19/2003 and issued as US patent JALISI-6,620,192.

As to claims 41-48, JALISI discloses a stent made of L-605, which material L-605 includes all elements as recited in the claims.

As to claims 49-50, because JASILI stent includes all the elements as claimed, JASILI stent must inherently possesses the features as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 13, 53 and 55 are rejected under 35 U.S.C. 103(a) as obvious over FARIABI (6,419,693) in view of JALISI-US application 09/270,403 (filed 03/16/1999), which has been allowed on 5/19/2003 and issued as US patent JALISI-6,620,192.

As to claim 1, FARIABI reference discloses stent 50 comprising cobalt, chromium and at least one radiopaque material (such as tungsten). FARIABI stent comprises all chemical elements of amended claim 1 of the instant invention. FARIABI discloses **all** elements of the stent as claimed in claim 1, except the characteristics of "main body is visible but does not obscure the underlying vessel morphology when subjected to imaging". Notice that radiopaque material tungsten (up to 20%) in FARIABI stent is in the same range of radiopaque material tungsten in this present invention (14-16% tungsten), Fariabi stent must inherently possess the same feature claimed in the present invention. Alternatively, JALISI-'192 (col. 3, lines 34-36) discloses making a radiopaque stent with any desired degree of opacity. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct a FARIABI stent as recited in the claim as one desire which is visible but does not obscure an underlying morphology when subjected to imaging by controlling the percentage of tungsten in the range up to 20%.

As to claims 2, 5-9 and 13, FARIABI (Fig. 5-7; abstract, lines 5-10; claim 1) discloses a radiopaque stent 50 of Cobalt-Chrome alloy comprising up to 20% of a radiopaque tungsten (W). Stent 50 comprises tubular main body defining undulating pattern with holes. Stent 50 is carried by catheter 51 to be deployed in blood vessel 57 and expandable by balloon 54 (Fig. 6).

As to claim 53, FARIABI discloses a stent made of a high-strength cobalt-chromium alloy such as L-605, which has an elongation of about 30% as disclosed is well known. For example,

JALISI-'192 (col. 3, lines 48-53), discloses a radiopaque stent including L-605 as a high strength alloy.

As to claims 3-4 and 55, FARIABI discloses substantially all structural limitations as recited in the claim, except for an unexpanded outside diameter, a second expanded diameter, and a wall thickness as recited in the claims. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make FARIABI stent to have the dimensions as recited in the claims, as this configuration would be within level of one of ordinary skill in the art to determine according to the size of a blood vessel, the size of a deployment catheter and the required radial strength of a stent.

Response to Amendment

The amendment filed on 4/18/2003 under 37 CFR 1.131 has been considered but is moot in view of the above rejection based on the same references Fariabi-6,419,693 and US application 09/270,403 (or WO 00 54704) now US Pat. 6,620,192. Notice that 09/270,403 (or WO 00 54704) now US Pat. 6,620,192 teaches high strength cobalt-chromium alloy L-605 and radiopaque material such as a platinum/a tantalum/a tungstens, to make a radiopaque stent.

Conclusion

The ground for rejection of the claims above is substantially the same as that of the previous office action and based on the same references as cited in the previous office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

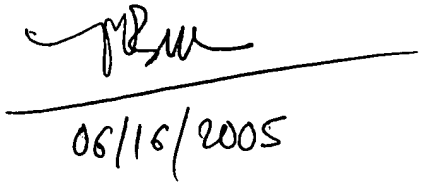
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



06/16/2005

Vy Q. Bui
Primary Examiner
Art Unit 3731